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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,900	03/07/2002	Muralidhara Padigaru	21402-290C (CURA 590C)	1049
7590	08/09/2004		EXAMINER KAPUST, RACHEL B	
Ivor R. Elrifi Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center Boston, MA 02111			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,900

Applicant(s)

PADIGARU ET AL.

Examiner

Rachel B. Kapust

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

RESPONSE TO AMENDMENT

Applicant's amendment filed May 25, 2004 is acknowledged. Claims 14-19 have been canceled. Claims 13 and 20 are amended. Claims 13 and 20-22 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the title of the invention as not being descriptive is withdrawn in response to Applicant's amendment to the title.

The rejection of claims 14 and 15 under 35 U.S.C. 112, first paragraph, for lack of written description, is withdrawn in response to Applicant's cancellation of these claims.

The rejection of claims 13 and 17-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is withdrawn in response to Applicant's amendment to claim 13 and the cancellation of claims 17-19.

The rejection of claims 17-22 under 35 U.S.C. 102(b) as being anticipated by Strausberg *et al.* is withdrawn in response to the cancellation of claims 17-19 and Applicant's amendment to claim 13.

Specification

It is noted that Applicants stated that they intend to file a supplemental amendment correcting the use of trademarks in the specification. At this time no supplemental amendment has been filed. Therefore, the objection to the specification regarding the use of trademarks as stated on p. 2 of the office action of paper no. 0204 is maintained.

Claim Rejections - 35 USC § 101

The rejection of claims 13 and 20-22 under 35 U.S.C. 101 is maintained for reasons of record on p. 3-4 of the office action of paper no. 0204.

Applicants argue on p. 6 of the response that the substantial asserted utility for the claimed nucleic acid molecules is that they can be employed as tools in cancer diagnosis because there is significant expression of the gene in cell lines derived from breast cancer tissue, brain cancer tissue, colon cancer tissue, and ovarian cancer tissue. Applicants refer to p. 705 of the specification which indicates “that the expression of the claimed sequence is dysregulated in cell lines derived from colon, brain, ovarian, and breast cancer” (p. 6 of response).

Applicants’ arguments have been fully considered but have not been found to be persuasive. As stated in the office action of paper no. 0204, tissue-specific expression such as that found on p. 705 is not specific to the claimed polynucleotide. It does not depend on any characteristics of the nucleic acid molecule itself. Regarding Applicants’ argument that because expression of the claimed nucleic acid sequence is dysregulated in cell lines it may be used as a marker in the diagnosis of cancer, the expression of markers often differs between expression in cell lines and actual expression in the patient’s cancerous tissue. Bover *et al.* (1998, Cell. Mol. Biol. 44(3): 493-504) teach that expression of markers was heterogeneous between an in vitro growing cell line and a xenotransplanted tumor growing in nude mice. An oncogene was amplified in the patient’s primary tumor, whereas no amplification was found in the corresponding cell line. Bover *et al.* teach that the differences between the patient’s tumor, the cell line, and the nude tumors are probably due to clonal expansion of cell variants not present in the original tumor. Accordingly, one of skill in the art would not know whether the nucleic acid of the claimed invention would be amplified in a real tumor or whether it is merely due to clonal expansion of a cell line. Further research would be required to determine how and if the claimed nucleic acid molecule is involved in any disease and whether or not it is a diagnostic marker for any disease.

Claim Rejections - 35 USC § 112

Claim 13 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As amended, claim 13 is drawn to a nucleic acid fragment encoding a polypeptide comprising at least a 40% portion of the amino acid sequence given SEQ ID NO: 112. While the original disclosure refers to nucleic acid fragments encoding a portion of SEQ ID NO: 112, the original disclosure does not refer to fragments encoding a polypeptide comprising at least a 40% portion of the amino acid sequence of SEQ ID NO: 112. Such nucleic acid fragments are considered to be new matter.

The rejection of claims 13 and 20-22 under 35 U.S.C. 112, first paragraph, because since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, and one skilled in the art would not know how to use the claimed invention, is maintained for reasons of record on p. 5 of the office action of paper no. 0204.

The rejection of claims 13 and 20-22 under 35 U.S.C. 112, first paragraph for lack of enablement for nucleic acid fragments encoding a polypeptide comprising at least a 40% portion of the amino acid sequence of SEQ ID NO: 112, is maintained for reasons of record on p. 5-6 of the office action of paper no. 0204.

Applicants argue that the pending claims are now not directed to an infinite number of variants, and one of skill in the art would be able to make and use the polynucleotides of the claimed invention without undue experimentation.

Applicants' arguments have been considered but have not been found to be persuasive. There is no functional limitation in the claims. Applicants have taught the polynucleotide encoding the polypeptide of SEQ ID NO: 112. However, Applicants provide little or no guidance beyond the mere presentation of sequence data to enable one of skill in the art to

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determine, without undue experimentation, the positions in the protein that are tolerant to change and the nature and extent of changes that can be made in these positions. Applicants have not asserted any activity for polypeptides comprising SEQ ID NO: 112. The encoded polypeptides comprising at least 40% of SEQ ID NO: 112 could have structures and functions that are very different from that of a polypeptide encoded by SEQ ID NO: 112. In addition, because there is no activity disclosed for the encoded polypeptide, there would be no means for predicting or identifying other polypeptides that would have a similar activity.

Due to the large quantity of experimentation necessary to generate the large number of variants recited in the claims and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

The rejection of claims 13 and 20-22 under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement is maintained for reasons of record on p. 7-8 of the office action of paper no. 0204.

Applicants argue that the pending claims are described by the as-filed specification in such a manner as to allow a person skilled in the art to conclude that Applicants had possession of the claimed invention.

Applicant's arguments have been considered but have not been found to be persuasive. Applicants have disclosed one species, the nucleic acid molecule consisting of SEQ ID NO: 111, but have not disclosed sufficient species for the broad genus which includes nucleic acid molecules encoding polypeptides comprising at least 40% of SEQ ID NO: 112. The claims do not require that the encoded polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of the protein has the disclosed activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Conclusion

NO CLAIMS ARE ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBK
8/5/04


JANET ANDRES
PRIMARY EXAMINER